

This report is required by law (7 USC 2143). Failure to report accurately to the regulations will result in an order to cease and desist and to be subject to penalties as provided for in Section 21:

Additional Information.

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0001  
CUSTOMER NUMBER: 158

FORM APPROVED  
OMB NO. 0579-0038

ANNUAL REPORT OF RESEARCH FACILITY  
(TYPE OR PRINT)

Bell Labs Lucent Technologies  
600 Mountain Avenue  
P. O. Box 636  
Murray Hill, NJ 07974

Telephone: (908) -582-5696

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reason such drugs were not used must be attached to this report)	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					0
5. Cats					0
6. Guinea Pigs					0
7. Hamsters					0
8. Rabbits					0
9. Non-human Primates		No covered species			0
10. Sheep					0
11. Pigs					0
12. Other Farm Animals					0
13. Other Animals					0

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

(NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print))

(DATE SIGNED)

1/20/04

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0005  
CUSTOMER NUMBER: 8203

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

N J State Dept Of Health  
Div. Of Pub Health & Env. Labs  
Cn 360  
Trenton, NJ 08625

SEP 29 2003

Telephone: (609)-292-5847

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

LAB BLDG. - PH+EL

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

\* DATE SIGNED

9/25/03

NOV 26 2003

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 211

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0006  
CUSTOMER NUMBER: 169

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
(TYPE OR PRINT)

Ortho Pharmaceutical Corporation  
Johnson & Johnson Pharmaceutical Rsrch & Dev, L.L.C.  
P O Box 300 Route 202 South  
Raritan, NJ 08869

Telephone: (908) -704-4310

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report).	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	50	370*	197*	34*	601
5. Cats	-	-	-	-	-
6. Guinea Pigs	12	729*	795*	30	1554
7. Hamsters	20	0	661*	446	1107
8. Rabbits	5*	0	183*	0	183
9. Non-human Primates	14*	16*	52*	0	68
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
(Chief Executive Officer or Legally Responsible Institutional Official)

DATE SIGNED

11-25-03

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**USDA ANNUAL REPORT (2002-2003)****Registration #: 22-R- 0006**

The following animals were reported on previous USDA Reports under License: 22-R-0006.

SPECIES	CATEGORY B	CATEGORY C	CATEGORY D	CATEGORY E
DOGS	0	170	154	18
GUINEA PIGS	0	8	141	0
HAMSTERS	0	0	122	0
RABBITS	5	0	53	0
NON-HUMAN PRIMATES	12	11	52	0



**USDA ANNUAL REPORT (2002-2003)****Registration #: 22-R- 0006****Animals Listed in Category E**

During the reporting period, Johnson & Johnson Pharmaceutical Research & Development, L.L.C. Institutional Animal Care and Use Committee (IACUC) approved the use of animals in Category E as follows:

<b><u>SPECIES</u></b>	<b><u>NUMBER</u></b>	<b><u>PROCEDURE/JUSTIFICATION</u></b>
Dogs	34	Single and repeat dose Pharmacokinetic/Toxicology studies as part of the Preclinical package submitted to the FDA for review and eventual drug approval. In these studies, animals may occasionally show mild emesis and short-term loss of appetite. It is important to determine if these clinical signs are reversible, as is often the case. Opioid analgesics alter GI motility and would be contraindicated. 1,2, 3
Guinea Pigs	30	Animals involved in studies on delayed hypersensitivity and anaphylaxis. These animals (controls) are used to evaluate potential asthma treatments and are thus exposed via aerosol to agents that cause mild, transient bronchospasm. 1
Hamster	446	Studies are used for evaluating anti-inflammatory compounds. Dorsal sub-cutaneous air pouch and paw edema models are utilized. 1

1 Administration of anesthetics, analgesics or tranquilizing drugs must be withheld so as not to invalidate the evaluation of test compounds.

2 Preclinical toxicology and drug metabolism/pharmacokinetic studies are required in nonhuman species by the Food and Drug Administration, Good Laboratory Practice Regulations – CFR 21, Part 58 (Code of Conduct).

3 Spied, L.H., Lunley, C.E. and S.R. Walker. "Harmonization of Guidelines for Toxicity Testing of Pharmaceuticals by 1992." Regulatory Toxicology and Pharmacology. Vol 12, pp 179-211 (1990).

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See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0009  
CUSTOMER NUMBER: 519

FORM APPROVED  
OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY**  
(TYPE OR PRINT)

Novartis Pharmaceuticals Corporation  
Bldg 437/1329  
One Health Plaza  
East Hanover, NJ 07936  
  
Telephone: (973) -781-0074

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report).	F. TOTAL NUMBER OF ANIMALS  (COLUMNS C + D + E)
4. Dogs	42	424	41	92	557
5. Cats					
6. Guinea Pigs					
7. Hamsters		876	7		883
8. Rabbits	9	522	52	47	621
9. Non-human Primates	210	344	69	52	465
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

**ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**  
(Chief Executive Officer or Legally Responsible Institutional Official)

DATE SIGNED

11-26-03

## OPTIONAL COLUMN E EXPLANATION FORM

### ORAL (GAVAGE) RISING DOSE/2-WEEK TOXICITY STUDY IN DOGS

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 4. Number of animals classified as category "E" - 2.
3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

Two dogs on this study experienced compound related effects and were euthanized unscheduled.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

## OPTIONAL COLUMN E EXPLANATION FORM

### INTRAVENOUS RISING DOSE TOXICITY STUDY IN DOGS WITH A 17-DAY RECOVERY PERIOD

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 6. Number of animals classified as category "E" - 1.
3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

One dog on this study experienced compound related effects.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

The clinical signs were not deemed so severe that intervention was necessary. This animal remained on study.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

## OPTIONAL COLUMN E EXPLANATION FORM

### 52-WEEK ORAL (CAPSULE) TOXICITY STUDY IN DOGS WITH A 4-WEEK RECOVERY PERIOD

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 40. Number of animals classified as category "E" - 22.
3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

Twenty two dogs experienced compound related effects such as diarrhea and emesis.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

The signs were not considered to be so severe that intervention was necessary.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

## OPTIONAL COLUMN E EXPLANATION FORM

### 26-WEEK ORAL (CAPSULE) TOXICITY STUDY IN DOGS WITH A 4-WEEK RECOVERY PERIOD

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 38. Number of animals classified as category "E" – 10.
3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

Ten dogs experienced compound related effects such as diarrhea primarily.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

The signs were not considered to be so severe that intervention was necessary.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

## OPTIONAL COLUMN E EXPLANATION FORM

### 26-WEEK ORAL (CAPSULE) TOXICITY STUDY IN DOGS WITH A 4-WEEK RECOVERY PERIOD

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 40. Number of animals classified as category "E" - 13.
3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

Thirteen dogs experienced compound related effects in this study. One was euthanized unscheduled and the signs for the others were not considered to be so severe that intervention was necessary.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

## OPTIONAL COLUMN E EXPLANATION FORM

### ORAL (GAVAGE) RISING DOSE/1-WEEK TOXICITY STUDY IN DOGS

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 6. Number of animals classified as category "E" - 5.
3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

Five dogs experienced compound related effects in this study and were euthanized unscheduled.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)



## OPTIONAL COLUMN E EXPLANATION FORM

### INTRAVENOUS RISING DOSE TOXICITY STUDY IN DOGS WITH A 16-DAY RECOVERY PERIOD

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 4. Number of animals classified as category "E" - 1.
3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

One dog experienced compound related effects in this study. This dog was euthanized on study day one.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

## OPTIONAL COLUMN E EXPLANATION FORM

### ORAL (GAVAGE) RISING DOSE/1-WEEK TOXICITY STUDY IN DOGS

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 6. Number of animals classified as category "E" - 6.
3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

Six dogs experienced compound related effects such in this study. One dog was found dead on study day 5 and three other dogs were euthanized unscheduled on study day 5. Two dogs were euthanized unscheduled on study days 7 and 9.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

**OPTIONAL COLUMN E EXPLANATION FORM**  
**ACUTE ORAL (GAVAGE) TOXICITY STUDY IN DOGS**

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 6. Number of animals classified as category "E" - 4.
3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

Four dogs on this study experienced compound related effects and were euthanized unscheduled.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

## OPTIONAL COLUMN E EXPLANATION FORM

### 4-WEEK ORAL (GAVAGE) TOXICITY STUDY IN DOGS WITH A 4-WEEK RECOVERY PERIOD

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 32. Number of animals classified as category "E" - 2.
3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

Two dogs experienced compound related effects such as diarrhea for more than 3-4 days in this study.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

The diarrhea resolved and intervention was not deemed necessary.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

## OPTIONAL COLUMN E EXPLANATION FORM

### EXPLORATORY 4-WEEK ORAL (GAVAGE) TOXICITY STUDY IN FEMALE DOGS

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 8. Number of animals classified as category "E" - 1.
3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

One dog on this study experienced compound related effects. It had diarrhea for more than one week.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

The signs were not considered to be so severe that intervention was necessary.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

## OPTIONAL COLUMN E EXPLANATION FORM

### 4-WEEK ORAL (GAVAGE) TOXICITY STUDY IN DOGS WITH A 4-WEEK RECOVERY PERIOD

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 32. Number of animals classified as category "E" - 10.
3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

Ten dogs experienced compound related effects in this study. The effects included diarrhea, ataxia and emesis greater than 3 days duration. One dog was euthanized unscheduled.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

The signs for the others were not considered to be so severe that intervention was necessary.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

## OPTIONAL COLUMN E EXPLANATION FORM

### 4-WEEK ORAL (GAVAGE) TOXICITY STUDY IN DOGS WITH A 4-WEEK RECOVERY PERIOD

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 32. Number of animals classified as category "E" - 11.
3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

Eleven dogs experienced compound related effects such as diarrhea and emesis. Four were euthanized unscheduled.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

The signs for the others were not considered to be so severe that intervention was necessary.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

**OPTIONAL COLUMN E EXPLANATION FORM**  
**ORAL (GAVAGE) RISING DOSE TOXICITY STUDY IN DOGS**

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 6. Number of animals classified as category "E" - 1.
3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

One dog experienced compound related effects in this study.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

The animal was found dead.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)



**OPTIONAL COLUMN E EXPLANATION FORM**  
**2-WEEK ORAL (GAVAGE) TOXICITY STUDY IN DOGS**

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 24. Number of animals classified as category “E” - 3.
3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

Three dogs on this study experienced compound related effects. They had emesis on more than 7 days of the study.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

The signs were not considered to be so severe that intervention was necessary.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

## OPTIONAL COLUMN E EXPLANATION FORM

### INTRAVENOUS RISING DOSE TOXICITY STUDY IN MONKEYS WITH A 16-DAY RECOVERY PERIOD

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 8. Number of animals classified as category "E" - 5.
3. Species (common name)\_\_\_Non-human Primate\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These primates were dosed with a pharmaceutical compound.

Five monkeys experienced skin irritations and lesions as a compound related effect.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

The lesions were treated topically or were not considered so severe that interventions was necessary.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

## OPTIONAL COLUMN E EXPLANATION FORM

### 4-WEEK ORAL (GAVAGE) TOXICITY STUDY IN MONKEYS WITH A 4-WEEK RECOVERY PERIOD

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 32. Number of animals classified as category "E" - 1.
3. Species (common name)\_\_\_Non-human Primate\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These primates were dosed with a pharmaceutical compound.

This monkey experienced decreased locomotor activity, dehydration and emesis as compound related effects. This monkey also experienced the compound related effect of emesis on seven of thirty days on study. Five of the seven days occurred within the same week.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

The purpose of this study was to determine the toxicity of the compound. In these cases, the relief of pain and/or distress would have defeated the purpose of the study.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

## OPTIONAL COLUMN E EXPLANATION FORM

### 4-WEEK ORAL (GAVAGE) TOXICITY STUDY IN MONKEYS WITH A 4-WEEK RECOVERY

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 32. Number of animals classified as category “E” - 8.
3. Species (common name)\_\_\_Non-human Primate\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These primates were dosed with a pharmaceutical compound.

Eight monkeys on this study experienced compound related effects. One was found dead, two were euthanized unscheduled and for the other five the clinical signs were not considered so severe that intervention was necessary.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as there were signs that animals were experiencing significant pain and distress they were euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

## OPTIONAL COLUMN E EXPLANATION FORM

### 39-WEEK ORAL (GAVAGE) TOXICITY STUDY IN MONKEYS WITH A 4-WEEK RECOVERY PERIOD

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 40. Number of animals classified as category "E" - 9.
3. Species (common name)\_\_\_Non-human Primate\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These primates were dosed with a pharmaceutical compound.

Nine monkeys experienced compound related effects on this study. One animal was found dead and seven were euthanized unscheduled. For one animal, the clinical signs were not deemed so severe that intervention was necessary. This animal is still on study.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

## OPTIONAL COLUMN E EXPLANATION FORM

### 10-DAY ORAL (GAVAGE) DOSE ESCALATION STUDY IN MARMOSETS

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 12. Number of animals classified as category "E" - 6.
3. Species (common name)\_\_\_Non-human Primate\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These primates were dosed with a pharmaceutical compound.

Six marmosets on this study experienced the compound related effect of emesis for more than three consecutive days.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

The purpose of this study was to determine the toxicity of the compound. In these cases, the relief of the emesis would have defeated the purpose of the study. Therefore the degree of distress experienced was justifiable.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

## OPTIONAL COLUMN E EXPLANATION FORM

### 1-WEEK ORAL (GAVAGE) TOXICITY STUDY IN MARMOSETS

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 16. Number of animals classified as category "E" - 1.
3. Species (common name)\_\_\_\_Non-human Primates\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These primates were dosed with a pharmaceutical compound.

One marmoset experienced compound related effects in this study. This marmoset had diarrhea with some blood in it for 3-4 days.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

Intervention was not deemed necessary.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

## OPTIONAL COLUMN E EXPLANATION FORM

### 2-WEEK ORAL (GAVAGE) DOSE RANGE-FINDING TOXICITY STUDY IN MARMOSETS

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 24. Number of animals classified as category "E" - 4.
3. Species (common name)\_\_\_\_Non-human Primates\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These animals were dosed with a pharmaceutical compound.

Four marmosets experienced compound related effects. Three of the four had emesis more than 3 days consecutively. One had decreased locomotor activity and poor body condition and had to be euthanized unscheduled on day 15 of dosing.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

The purpose of this study was to determine the toxicity of the compound. As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)



## OPTIONAL COLUMN E EXPLANATION FORM

### 4-WEEK NASOGASTRIC (GAVAGE) TOXICITY/COMBINATION STUDY IN MONKEYS WITH NEORAL<sup>®</sup> AND A 4-WEEK RECOVERY PERIOD

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 44. Number of animals classified as category "E" - 6.
3. Species (common name)\_\_\_\_ Non-human Primates\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These animals were dosed with a pharmaceutical compound.

Six monkeys on this study experienced compound related effects. One was found dead and the clinical signs for the others were not considered so severe that intervention was necessary.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

The clinical signs for five monkeys were not considered so severe that intervention was necessary.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).

## OPTIONAL COLUMN E EXPLANATION FORM

### 2-WEEK ORAL (GAVAGE) DOSE RANGE-FINDING STUDY IN MONKEYS

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 10. Number of animals classified as category "E" - 2.
3. Species (common name) \_\_\_\_\_ Non-human Primates \_\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These animals were dosed with a pharmaceutical compound.

Two cynomolgus monkeys experienced the compound related effects of decreased food consumption, decreased locomotor activity, abnormal posture, ataxia and recumbency. They were euthanized on day 5 and 12.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

It was determined that the degree of pain and/or distress recognized in the monkeys justified unscheduled euthanasia.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).

## OPTIONAL COLUMN E EXPLANATION FORM

### INTRAVENOUS DOSE RANGE-FINDING STUDY IN MONKEYS

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 10. Number of animals classified as category "E" - 4.
3. Species (common name)\_\_\_\_Non-human Primates\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These animals were dose with a pharmaceutical compound.

Four Cynomolgus monkeys on this study experienced compound related effects. One was found dead on day 8 of dosing and the other three were euthanized unscheduled, two on study day 3 and one on study day 9.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

The purpose of this study was to determine the toxicity of the compound. As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).

## OPTIONAL COLUMN E EXPLANATION FORM

### 2-WEEK NASOGASTRIC (GAVAGE) DOSE RANGE-FINDING COMBINATION STUDY IN MALE MONKEYS

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 12. Number of animals classified as category "E" - 4.
3. Species (common name)\_\_\_\_ Non-human Primates\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These animals were dosed with a pharmaceutical compound.

Four monkeys experienced compound related effects. One was found dead and three were euthanized unscheduled.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).

## OPTIONAL COLUMN E EXPLANATION FORM

### ORAL (GAVAGE) RISING DOSE TOXICITY STUDY IN MONKEYS

1. Registration Number: 22-R-0009
2. Number of animals used in this study -2. Number of animals classified as category "E" - 2.
3. Species (common name)\_\_\_\_Non-human Primates\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These animals were dosed with a pharmaceutical compound.

The two monkeys on this study experienced compound related effects. The monkeys were euthanized after they were observed in a moribund condition.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).

## OPTIONAL COLUMN E EXPLANATION FORM

### ORAL EMBRYO-FETAL DEVELOPMENT STUDY IN RABBITS

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 80. Number of animals classified as category "E" - 23.
3. Species (common name)\_\_\_\_Rabbits\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These animals were dosed with a pharmaceutical compound.

Twenty-three rabbits in this study experienced compound related effects. One was found dead and the others had ataxia and some recumbency.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

The signs were not considered to be so severe that intervention was necessary.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).
- 2) Guideline on detection of toxicity to reproduction for medicinal products published in the Federal Register on September 22, 1994 (FR 48746).

## OPTIONAL COLUMN E EXPLANATION FORM

### ORAL EMBRYO-FETAL DEVELOPMENT DOSE RANGE-FINDING STUDY IN RABBITS

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 30. Number of animals classified as category "E" - 1.
3. Species (common name) \_\_\_\_\_ Rabbits \_\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These animals were dosed with a pharmaceutical compound.

One rabbit in this study experienced compound related effects and was euthanized after it was observed in a moribund condition.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).
- 2) Guideline on detection of toxicity to reproduction for medicinal products published in the Federal Register on September 22, 1994 (FR 48746).

**OPTIONAL COLUMN E EXPLANATION FORM**  
**EMBRYO-FETAL DEVELOPMENT STUDY IN RABBITS**

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 80. Number of animals classified as category "E" - 1.
3. Species (common name) \_\_\_\_\_ Rabbits \_\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These animals were dosed with a pharmaceutical compound.

One rabbit in this study experienced a compound related effect. This rabbit was euthanized after being found recumbent with labored breathing.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

This animal was euthanized once signs indicating pain and distress were observed.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).
- 2) Guideline on detection of toxicity to reproduction for medicinal products published in the Federal Register on September 22, 1994 (FR 48746).



## OPTIONAL COLUMN E EXPLANATION FORM

### ORAL EMBRYO-FETAL DEVELOPMENT DOSE RANGE FINDING STUDY IN RABBITS

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 30. Number of animals classified as category "E" - 6.
3. Species (common name) \_\_\_ Rabbits \_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These animals were dosed with a pharmaceutical compound.

Six animals on this study experienced compound related effects. Five were found dead and one was euthanized unscheduled.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as signs of pain or distress were observed, the animals were euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).
- 2) Guideline on detection of toxicity to reproduction for medicinal products published in the Federal Register on September 22, 1994 (FR 48746).

## OPTIONAL COLUMN E EXPLANATION FORM

### ORAL EMBRYO-FETAL DEVELOPMENT DOSE RANGE FINDING STUDY IN RABBITS

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 15. Number of animals classified as category "E" - 15.
3. Species (common name)\_\_\_\_Rabbits\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These animals were dosed with a pharmaceutical compound.

Fifteen rabbits on this study experienced compound related effects. Six were found dead and the others were euthanized unscheduled.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as signs of pain or distress were observed, the animals were euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).
- 2) Guideline on detection of toxicity to reproduction for medicinal products published in the Federal Register on September 22, 1994 (FR 48746).

## OPTIONAL COLUMN E EXPLANATION FORM

### 2-CYCLE INTRAVENOUS EMBRYO-FETAL DEVELOPMENT DOSE RANGE-FINDING STUDY

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 15. Number of animals classified as category “E” - 6.

3. Species (common name) \_\_\_\_\_ Rabbits \_\_\_\_\_ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

These animals were dosed with a pharmaceutical compound.

Six rabbits experienced compound related effects during the 2003 reporting year. One animal was found dead and the others were euthanized unscheduled.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as signs of pain or distress were observed, the animals were euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).
- 2) Guideline on detection of toxicity to reproduction for medicinal products published in the Federal Register on September 22, 1994 (FR 48746).

**USDA ANNUAL REPORT OF RESEARCH FACILITY FOR 2003**  
**NOVARTIS PHARMACEUTICALS CORPORATION**  
**USDA Registration No. 22-R-0009**

Summary of the NACUC approved exceptions to the Standards and Regulations:  
 Canine Exercise Exemptions

	<u>Protocol Title</u>	<u>Species</u>	<u>Number</u>	<u>Days Without Exercise</u>	<u>Reason</u>
1.	Absorption, Metabolism and Excretion After A Single Oral or IV Dose in the Dog	Dogs	08	7	Quantitative collection of excreta, containment of radioactivity
2.	Absorption, Metabolism and Excretion After A Single Oral or IV Dose in the Dog	Dogs	07	4	Quantitative collection of excreta, containment of radioactivity
3.	Absorption, Metabolism and Excretion After A Single Oral or IV Dose in the Dog	Dogs	02	9	Quantitative collection of excreta, containment of radioactivity
4.	Absorption, Metabolism and Excretion After A Single Oral or IV Dose in the Dog	Dogs	42	15	Treatment of Giardia
5.	Absorption, Metabolism and Excretion After A Single Oral or IV Dose in the Dog	Dogs	01	30	Possible Transmissible Infection
6.	Telemetry Device Implantation and Holding Protocol for Dogs and Monkeys Intended for Use on Safety Pharmacology Studies	Dogs	2	14	Surgical recovery of dogs implanted with telemetry devices

	<u>Protocol Title</u>	<u>Species</u>	<u>Number</u>	<u>Days Without Exercise</u>	<u>Reason</u>
7.	Telemetry Device Implantation and Holding Protocol for Dogs and Monkeys Intended for Use on Safety Pharmacology Studies	Dogs	5	12	Surgical recovery of dogs implanted with telemetry devices
8.	Telemetry Device Implantation and Holding Protocol for Dogs and Monkeys Intended for Use on Safety Pharmacology Studies	Dogs	7	10	Surgical recovery of dogs implanted with telemetry devices
9.	Telemetry Device Implantation and Holding Protocol for Dogs and Monkeys Intended for Use on Safety Pharmacology Studies	Dogs	1	13	Surgical recovery of dogs implanted with telemetry devices

DEC 01 2003

See attached form for additional information.

Interagency Report Control No. *RSM*

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0013  
CUSTOMER NUMBER: 163

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

Worldwide Mobile Veterinary Unit  
8 Foxhunt Drive  
Rockaway, NJ 07866

Telephone: (973) -361-5428

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F. TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs			18		18
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

DATE SIGNED

11/24/03

NOV 21 2003

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0016  
CUSTOMER NUMBER: 174

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

Johnson & Johnson Consumer Products, Inc.  
Johnson & Johnson Res. Found.  
Research & Development  
199 Grandview Road  
Skillman, NJ 08558

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs		12	7		19
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inx brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )

DATE SIGNED

11/19/03

NOV 26 2003

See attached form for additional information.

Interagency Report Control No. *Jan*

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0020  
CUSTOMER NUMBER: 175

FORM APPROVED  
OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY**  
( TYPE OR PRINT )

University Of Medicine & Dentistry Of New Jersey  
New Jersey Medical School  
185 S. Orange Avenue  
Msb A-604  
Newark, NJ 07101

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )**

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs			41		41
5. Cats			6		6
6. Guinea Pigs		15			15
7. Hamsters		5	25		30
8. Rabbits		2	124		126
9. Non-human Primates			8		8
10. Sheep					
11. Pigs			94		94
12. Other Farm Animals					
13. Other Animals					
Woodchucks			23		23

**ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIGNAT

DATE SIGNED

11/20/03



DEC 01 2003

See attached form for additional information.

Interagency Report Control No. *sp*

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0022  
CUSTOMER NUMBER: 176

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

Princeton University  
Office Of Research & Projects  
P.O. Box 36  
Princeton, NJ 08544

Telephone: (609) -258-3090

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					
5. Cats			16		16
6. Guinea Pigs					
7. Hamsters					
8. Rabbits			33		33
9. Non-human Primates	3	6	16		22
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Marmosets			37		37

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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APR 2003

DATE SIGNED

11/25/03

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0025  
CUSTOMER NUMBER: 177

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

Rutgers-State University Of Nj  
Research & Sponsored Programs  
3 Rutgers Plaza  
New Brunswick, NJ 08901

DEC 05 2003

Telephone: (732) -932-0150

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F. TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	16		58		58
5. Cats			27		27
6. Guinea Pigs		409	251		660
7. Hamsters					
8. Rabbits	14	4	10		14
9. Non-human Primates			5		5
10. Sheep					
11. Pigs			8		8
12. Other Farm Animals					
Deer		22			22
13. Other Animals					
Ferrets		2			2
Gerbils		38			38
Spiny Mice		2			2

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

E SIGNED

*26-03*

Customer ID and Site Address:

ID: 177

3559d Nelson Labs &  
Annex  
604 Allison Road  
Piscataway, NJ 08854  
County: Middlesex

Telephone

Customer ID and Site Address:

ID: 177

Telephone

P.O. Box 1059

Bldg 7002 Science

Camden, NJ 08101

County: Camden

Customer ID and Site Address:

ID: 177

Psarf Complex &  
Bartlett Hall

New Brunswick, NJ 08901

County: Middlesex

Telephone

Customer ID and Site Address:

ID: 177

197 University Avenue

Newark, NJ 07102

County: Essex

Telephone

DEC 01 2003

See attached form for additional information.

Interagency Report Control No. *df*

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0030  
CUSTOMER NUMBER: 178

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

Merck & Company, Inc.  
126 E Lincoln Avenue  
Po Box 2000 Ry80m-101  
Rahway, NJ 07065

Telephone: (732) -594-3430

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquil drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	3	749	1061	1	1811
5. Cats	0	35	0		35
6. Guinea Pigs	66	2288	467		2755
7. Hamsters	59	377	65		442
8. Rabbits	18	2440	873	66	3379
9. Non-human Primates	3778	188	877		1065
10. Sheep					
11. Pigs	20	39	88		127
12. Other Farm Animals					
Horses	1	1	3		4
13. Other Animals					
Ferrets		24	200		224
Gerbils		0	32		32

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIGNATURE

APHIS Form 7023A  
( AUG 91 )

DATE SIGNED

11/22/03

*CLIN*

USDA Annual Report: October 1, 2002-September 30, 2003

Registration Number 22-R-0030; Merck & Co., Inc

This report includes animals housed or used at the following sites:

126 E. Lincoln Avenue  
Rahway NJ 07065-4607  
COUNTY: UNION

Telephone:  
(732) 594-6179

203 River Rd  
Somerville NJ 08876  
COUNTY: SOMERSET

Telephone:  
(908) 685-3846

RD 1 Box 391  
Oxford NJ 07863  
COUNTY: WARREN

Telephone: (Inactivated September 17, 2003)  
(908) 637-4427

3535 General Atomics Ct  
San Diego CA 92121-1140  
COUNTY: SAN DIEGO

Telephone:  
(858) 202-5466

WP44-201  
West Point PA 19486-0004  
COUNTY: MONTGOMERY

Telephone:  
(215) 652-6232

WP74-1  
West Point PA 19486-0004  
COUNTY: MONTGOMERY

Telephone:  
(215) 652-6093

PO Box 016960 (R289)  
Miami FL 33136  
COUNTY: DADE

Telephone: (Inactivated April 16, 2003)  
(305) 243-8912

20256 SW 360<sup>th</sup> St  
Homestead FL 33034-4102  
COUNTY: DADE

Telephone:  
(305) 245-1551

PO Box 549  
Alice TX 78333  
COUNTY: JIM WELLS

Telephone: (Inactivated April 16, 2003)  
(361) 664-4984

95 Castle Hall Road  
Yemassee SC 29945  
COUNTY: BEAUFORT

Telephone: (Inactivated April 16, 2003)  
(843) 589-5190

466 Devon Park Drive  
Wayne PA 19087  
COUNTY: CHESTER

Telephone:  
(215) 652-6232

New Iberia Research Center  
University of Louisiana  
4401 W. Admiral Doyle Drive  
New Iberia LA 70560  
COUNTY: IBERIA

Telephone: (Inactivated April 16, 2003)  
(337) 482-0250



USDA Annual Report: October 1, 2002-September 30, 2003

Registration Number 22-R-0030; Merck & Co., Inc

Explanation of items in column E:

One dog experienced unanticipated distress for less than one hour after oral test compound administration for an IACUC-approved research protocol. The dog was examined by a veterinarian and subsequently euthanized. The use of anesthetics, analgesics or tranquilizers would have adversely affected the interpretation of results.

Studies were conducted in rabbits to evaluate the efficacy of novel antibacterial compounds. After being administered a known microbial agent, sixty-six rabbits experienced mild to moderate discomfort for less than 8 hours. Established antibacterial compounds and pain-relieving agents could not be administered because they would prevent assessment of the experimental compounds and defeat the purpose of the research. The minimum numbers of animals were used to provide reliable test results. These procedures were reviewed and approved by the IACUC and monitored by a veterinarian.

USDA Annual Report: October 1, 2002-September 30, 2003

Registration Number 22-R-0030; Merck & Co., Inc

IACUC-approved exceptions to the standards and regulations:

One dog was exempted from the approved dog exercise plan because it was being treated and observed during a post-operative period that lasted for five days.

Nine dogs were exempted from the approved dog exercise plan because they required urine/feces collection for five days after radioactive isotopes were administered.

One dog was exempted from the approved dog exercise plan on two occasions because it required urine/feces collection for five days after radioactive isotopes were administered. The animal was provided with the opportunity to exercise for 24 hours between the first occasion for exemption and the second occasion for exemption.

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0031  
CUSTOMER NUMBER: 179

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
(TYPE OR PRINT)

Newark Beth Israel Medical Center  
201 Lyons Avenue  
Newark, NJ 07112

Telephone: (973) 926-7311

OCT 24 2003

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	7		52		52
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs	0		14		14
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

SLK

APF

(AUG91)

DATE SIGNED

10/22/03

NOV 28 2003

See attached form for additional information.

Interagency Report Control No. 7

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0032  
CUSTOMER NUMBER: 180

FORM APPROVED  
OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY**  
( TYPE OR PRINT )

Hoffmann-La Roche, Inc.  
Research & Development Div.  
340 Kingsland Street  
Nutley, NJ 07110

Telephone: (973) -235-5000

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F. TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	63	294	5	0	299
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	5	10	0	15
7. Hamsters	0	0	0	0	0
8. Rabbits	0	239	1	5	245
9. Non-human Primates	34	18	16	0	34
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

**ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIG

DATE SIGNED

11/24/03

*Q97*

### Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 22-R-0032

2. Number \_\_\_\_\_ of animals used in this study.

3. Species (common name) Rabbit of animals used in the study.

4. Explain the procedure producing pain and/or distress.

A total of 5 rabbits from a group used in studies to evaluate drug candidates for clinical trials were identified as Category E. The rabbits were used to evaluate a HIV inhibitor compound and found dead without prior clinical signs.

The studies were designed and conducted in accordance with the FDA guidelines. Veterinary personnel observed all animals daily and provides supportative care when needed.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency FDA CFR 58.1

DEC 08 2003

Attached form for additional information

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0037  
CUSTOMER NUMBER: 752

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

Rider University  
2083 Lawrenceville Road  
Lawrenceville, NJ 08648  
Telephone: (609) -896-5010

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS Science & Technology Center - Room S-151

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, experiments, research, or surgery but not yet	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primate					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
spiny mice		275			275

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIG:

DATE SIGNED  
12/1/03

DEC 10 2003

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0038  
CUSTOMER NUMBER: 677

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

Bracco Research Usa, Inc.  
305 College Road East  
Princeton, NJ 08540

Telephone: (609) -514-~~2437~~ *2524* or *-240 99*

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

*Same address as above.*

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals			(Only rats and mice bred for research used)		

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

DATE SIGNED

*Dec 9 03*

NOV 20 2003

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0040

CUSTOMER NUMBER: 689

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

Huntingdon Life Sciences, Inc.  
P.O. Box 2360  
East Millstone, NJ 08875

Telephone: (732) -873-2550

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F. TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	19	180	128	9	317
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	0	113	24	7	144
9. Non-human Primates	62	229	86	28	343
10. Sheep					
11. Pigs	0	68	6	0	74
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

DATE SIGNED

11/19/03

5192



**Annual Report of Research Facility**  
**October 1, 2002 to September 30, 2003**  
**Huntingdon Life Sciences**  
**Registration Number 22-R-0040**

**A) Explanation of Category E Studies**

All studies listed were conducted to conform to federally mandated requirements, promulgated by the US Food and Drug Administration (FDA). These regulations specify preclinical testing requirements necessary for approval of new drugs. Specific regulations include the following:

- 21 CFR 310, New Drugs
- 21 CFR 312.22, Investigational New Drugs/Biologics
- 21 CFR 314, Application for FDA Approval to Market a New Drug or Antibiotic Drug
- M3 Nonclinical Safety Studies for the Conduct of Clinical Trials in Pharmaceuticals – Guidance for Industry, US Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), July 1997
- Guidelines for General Pharmacology Studies (Japan Ministry of Health, Labor and Welfare PAB/NDD Notification No. 4, 29 January 1991)
- International Conference on Harmonization (ICH) Guideline Topic S7, Safety Pharmacology

For all studies listed below, the Principal Investigator provided written justification to the Huntingdon Life Sciences Institutional Animal Care and Use Committee that agents may not be used to alleviate pain or distress due to their potential for interference with the compound under investigation. Use of these agents was withheld so as not to invalidate the evaluation of test compounds, which could result in unnecessary duplication of research, and use of animals in number beyond that which is minimally required.

<b>Species</b>	<b>Number of Category E Animals</b>	<b>Description</b>
Rabbits	7	Animals were exposed to test compound via oral administration, for 14 days. Test article effects were evident in 7 animals. Affected animals were humanely euthanized.
Dogs	5	Animals were exposed to test compound via oral administration, for 28 days. Test article effects were evident in 5 animals. Affected animals were humanely euthanized.
Dogs	2	Animals were exposed to test compound via intravenous administration once. Test article effects were evident in 2 animals. Dose was discontinued in both affected animals.
Dogs	2	Animals were exposed to test compound via intravenous administration once. Test article effects were evident in 2 animals. Both affected animals were humanely euthanized.
Primate	8	Animals were exposed to test compound via intravenous administration for 8 days. Test article effects of brief duration resolved spontaneously in 8 affected animals.
Primate	1	Animals were exposed to test compound via intravenous administration, once per week for 4 weeks. Test article effects of brief duration resolved spontaneously in 1 affected animal.

**Annual Report of Research Facility  
October 1, 2002 to September 30, 2003  
Huntingdon Life Sciences  
Registration Number 22-R-0040**

<b>Species</b>	<b>Number of Category E Animals</b>	<b>Description</b>
Primate	10	Animals were exposed to test compound via oral administration for 28 days. Test article effects were evident in 10 animals. Four of the affected animals were humanely euthanized.
Primate	7	Animals were exposed to test compound via intravenous administration, four times over a 2-week period. Test article effects of brief duration resolved spontaneously in 7 affected animals.
Primate	2	Animals were exposed to test compound via oral administration for 28 days. Test article effects were evident in 2 animals. Both affected animals were humanely euthanized.

**B) Summary of IACUC-approved exceptions to the Standards and Regulations:**

- 13 dogs were exempted from the exercise requirement for 18 days during surgical recovery and data collection via subcutaneous telemetry implant.
- 14 dogs were exempted from the exercise requirement for 10 days during surgical recovery and 12 of these dogs were also exempted from the exercise requirement for an additional 9 days during data collection via subcutaneous telemetry implant.
- 6 dogs were exempted from the exercise requirement for 5 days during surgical recovery.
- 14 dogs were exempted from the exercise requirement for 10 days due to surgical recovery and 12 of these dogs were also exempted from the exercise requirement for an additional 29 days during data collection via subcutaneous telemetry implant.
- 59 dogs were exempted from the exercise requirement for 21 days during surgical recovery.

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0041

CUSTOMER NUMBER: 173

FORM APPROVED  
OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY**  
( TYPE OR PRINT )

Becton Dickinson And Co.  
One Becton Drive  
Franklin Lakes, NJ 07417

Telephone: (201) -847-6800

DEC 17 2003

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F. TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	0				0
5. Cats	0				0
6. Guinea Pigs	0	1730			1730
7. Hamsters	0				0
8. Rabbits	0	289	18		307
9. Non-human Primates	0				0
10. Sheep	0				0
11. Pigs	0		579		579
12. Other Farm Animals	0				0
13. Other Animals	0				0

**ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

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SIGNED

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30 Oct. 03

Customer ID and Site Address:

ID: 173

21 Davis Drive

Research Triangle Pa, NC 27709

County: Durham

Telephone

(919)597-6151

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 21-R-0061  
CUSTOMER NUMBER: 322

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

Hobart And William Smith Colleges  
Eaton Hall Biology Dept  
Geneva, NY 14456

Telephone: (315) -781-3586

*OCT 06 2003*

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquillizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					
5. Cats		24 preserved specimens			24
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

OFFICIAL ( Type or Print )

DATE SIGNED

*10/2/03*

**Customer ID and Site Address:**

ID: 322

Eaton Hall Biology  
Dept.

Geneva, NY 14456  
County: Ontario

Telephone  
(315)781-3586

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0064  
CUSTOMER NUMBER: 182

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

Ortho-Clinical Diagnostics, Inc.  
Regulatory & Clinical Affairs  
1001 U.S. Highway 202  
Raritan, NJ 08869

Telephone: (908) -218-8177

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F. TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	0	114	233	0	347
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
Goats	2	16	3	0	19
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary in brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

DATE SIGNED

## APHIS Form 7023A Site List

The following sites have been reported by the facility:

---

Registration Number:	22-R-0064
Customer Number:	182
Facility:	Ortho-Clinical Diagnostics, Inc. Regulatory Affairs 1001 U.S. Highway 202 Raritan, NJ 08869 (908) 218-8177

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Ortho-Clinical Diagnostics, Inc.  
Building K  
1001 U.S. Highway 202  
Raritan, NJ 08869

Robert Wood Johnson-Pharmaceutical Research Institute  
Farming Complex (RWJ-PRI)  
County Highway 513  
Pittstown, NJ 08868



UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0066  
CUSTOMER NUMBER: 184

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

University Of Medicine & Dentistry Of Nj  
Robert W. Johnson Med. School  
675 Hoes Lane  
Piscataway, NJ 08854

Telephone: (732)-235-4687

OCT 24 2003

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs		4	13		17
5. Cats					
6. Guinea Pigs			2		2
7. Hamsters					
8. Rabbits		32	168		200
9. Non-human Primates					
10. Sheep		3	2		5
11. Pigs			59		59
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIGNATURE OF CEO OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

10/24/03

Customer ID and Site Address:

ID: 184

UMDNJ-RWJMS

Basic Science Building-Research Tower  
675 Hoes Lane, RB01  
Piscataway, NJ 08854-5635  
County: Middlesex

Phone: 732-235-4570

UMDNJ-RWJMS

Medical Education Building  
One Robert Wood Johnson Place  
New Brunswick, NJ 08901-0019  
County: Middlesex

Phone: 732-235-7913

UMDNJ-RWJMS

Education and Research Building  
401 Haddon Avenue  
Camden, NJ 08103  
County: Camden

Phone: 856-757-9650

**University of Medicine and Dentistry of New Jersey  
Robert Wood Johnson Medical School**

Amendment to Annual Report of Research Facility  
Certificate Number: 22-R-0066  
Customer Number: 184

Section 3.128 Space Requirements. Enclosures shall be constructed and maintained so as to provide sufficient space to allow each animal to make normal postural and social adjustments with adequate freedom of movement.

Exception: An exception to the standard found in Section 3.128 was requested by the principal investigator based upon scientific necessity and was granted by the IACUC. The explanation is summarized as follows: During observation periods lasting 8 to 12 hours and during a drug infusion period of 48 hours, each pig needs to be confined in a metabolic cage that restricts its horizontal movements. The metabolic cage measures 1.5' wide, 3' long and is 4' high. The pig will be able to stand or recline but will have restricted movement so as not to pull out the pulmonary artery and aortic catheter which would result in exsanguination of the drug infusion catheter. The maximum period of time any individual pig would be confined to the metabolic cage would be 56 hours. The pigs will be transferred to a holding cage with approximately 18 square feet of floor space when they are not being experimentally observed and not being infused.

1/12/04

\_\_\_\_\_  
Date

NOV 24 2003

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0069  
CUSTOMER NUMBER: 185

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

Consumer Product Testing Co., Inc.  
70 New Dutch Lane  
Fairfield, NJ 07004

Telephone: (201) -808-7111  
973

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	-----	-----	-----	-----	-----
5. Cats	-----	-----	-----	-----	-----
6. Guinea Pigs	307	3307	0	162	3469
7. Hamsters	1	6	0	0	6
8. Rabbits	15	1392	0	152	1543
9. Non-human Primates	-----	-----	-----	-----	-----
10. Sheep	-----	-----	-----	-----	-----
11. Pigs	-----	-----	-----	-----	-----
12. Other Farm Animals	-----	-----	-----	-----	-----
13. Other Animals	-----	-----	-----	-----	-----

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIGN

DATE SIGNED

11/21/03

APHIS

( AUG 91 )

092



EST. 1975

# Consumer Product Testing Co.

Facility Registration Number: 22-R-0069

The animals listed in Column E of APHIS Form 7023 included 162 guinea pigs and 152 rabbits. The rabbits were used on irritation studies. These studies are used to determine the dermal or ocular irritation potential of the articles tested. The guinea pigs were used on sensitization studies. These studies were used to determine the sensitization potential of the products tested.

In all cases the "procedures producing pain or distress" were either the injection of an adjuvant or the application of an irritating substance to the animal(s) in question. The sponsors of these studies had indicated that the use of anesthetics or analgesics might have interfered with the interpretation of the test results.

As a contract facility, we are not always aware of the nature of the articles being tested and rely upon our sponsors to responsibly determine the appropriateness of the use of anesthetics and/or analgesics.

At the USDA's suggestion, we have included in Column E animals exhibiting maximum irritation scores in the above mentioned study types but not necessarily having exhibited behavioral responses normally associated with pain or distress. In cases where an animal had exhibited a behavioral response normally associated with pain or distress, the response was no more than momentary but the procedure was recorded as "painful" nonetheless.

OCT 09 2003

See attached form for additional information.

Interagency Report Control No. *9*

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0076

FORM APPROVED  
OMB NO. 0579-0036

CUSTOMER NUMBER: 189

**ANNUAL REPORT OF RESEARCH FACILITY**  
( TYPE OR PRINT )

Camden County College  
P.O. Box 200  
College Drive  
Blackwood, NJ 08012

Telephone: <sup>856</sup>~~(609)~~ -227-7200

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )**

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	8	0	8	0	8
7. Hamsters	0	0	0	0	0
8. Rabbits	12	0	12	0	12
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

**ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )

DATE SIGNED

10/1/03

Customer ID and Site Address:

ID: 189

Animal Science ~~Barn~~ - Truman 129 Telephone (856) 227-7200  
Camden County  
College  
Blackwood, NJ 08012  
County: Camden

FEB 05 2004

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0082

CUSTOMER NUMBER: 190

FORM APPROVED  
OMB NO. 0579-0036

*Amended*  
ANNUAL REPORT OF RESEARCH FACILITY  
(TYPE OR PRINT)

Product Safety Labs, Inc.  
2394 Route 130  
Dayton, NJ 08810

Telephone: (732)-438-5100

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs		5741		700	6441
7. Hamsters		88			88
8. Rabbits		1387	20	109	1516
9. Non-human Primate					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
<i>Ferrets</i>		187			187

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

DATE SIGNED

2/3/04

*for*



UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0082  
CUSTOMER NUMBER: 190

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
(TYPE OR PRINT)

Product Safety Labs, Inc.  
2394 Route 130  
Dayton, NJ 08810

Telephone: (732) 438-5100

NOV 20 2003

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs		5741			6441
7. Hamsters		88			88
8. Rabbits		1387	20	109	1516
9. Non-human Primate					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Ferrets		187			187

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATURE OF CEO OR INSTITUTIONAL OFFICIAL

DATE SIGNED

11/19/03

**ATTACHMENT TO USDA/APHIS ANNUAL REPORT OF RESEARCH FACILITY**  
**EXPLANATION OF COLUMN "E" ENTRIES**

10/01/02 through 9/30/03

**102 Rabbits – Eye Irritation Test (OPPTS 870.2400):** Thirteen (13) of these animals vocalized following instillation of the test compound but immediately became calm after they were returned to their cage. Therefore, anesthetic was not considered. Although the remaining animals (89) did not exhibit overt signs of pain or distress, they exhibited ocular irritation scores above an arbitrary threshold and were considered to be in distress as a result of their exposure to the test compound. Although in the eye irritation test ocular anesthetic may be used prior to instillation, repeated and/or prolonged anesthetic use could retard healing and possibly lead to collateral irritation and/or subsequent corneal infection. Therefore, ocular anesthetic was not used on the animals evidencing ocular irritation scores above this established threshold limit.

**7 Rabbits – Dermal Irritation Test (OPPTS 870.2500):** All animals exhibited eschar and/or corrosion at the dose site, which could indicate possible necrosis of the skin. In all cases, the area of exposure and subsequent skin damage was  $\leq 1$  in<sup>2</sup>. Continuous or prolonged use of topical or systemic anesthetic agents during dermal irritation tests was not considered appropriate since it could lead to study complications including increased irritation and delayed healing. The use of analgesic agents would be inappropriate in these studies due to resultant anti-inflammatory effects that could mask the indicators of irritation. If used, they might significantly alter the effects of the test compound and compromise study results.

**700 Guinea Pigs – Dermal Sensitization Test (OPPTS 870.2600):** Similar to the dermal irritation test noted above, these animals exhibited eschar and/or corrosion at the dose site, which could indicate possible necrosis of the skin. In all cases, the area of exposure and subsequent skin damage was  $\leq 1$  in<sup>2</sup>. Continuous or prolonged use of topical or systemic anesthetic agents during dermal sensitization tests was not considered appropriate since it could lead to study complications including increased irritation and delayed healing. The use of analgesic agents would be inappropriate in these studies due to resultant anti-inflammatory effects that could mask the indicators of sensitization. If used, they might significantly alter the effects of the test compound and compromise study results.

DEC 01 2003

See attached form for additional information.

Interagency Report Control No.: *PSM*

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0099  
CUSTOMER NUMBER: 194

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

University Of Medicine & Dentistry Of Nj  
School Of Osteopathic Medicine  
2 Medical Center Drive  
Stratford, NJ 08084

Telephone: (856) -566-6119

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquillizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					0
5. Cats					0
6. Guinea Pigs					0
7. Hamsters					0
8. Rabbits					0
9. Non-human Primates					0
10. Sheep					0
11. Pigs					0
12. Other Farm Animals					0
13. Other Animals					0

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIG

DATE SIGNED

11/25/03

DEC 02 2003

See attached form for additional information.

Interagency Report Control No.:

R8M

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0104  
CUSTOMER NUMBER: 198

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

Center For Molecular Med & Immunology  
520 Bellville Ave  
Belleville, NJ 07109

Telephone: (973) -844-7000

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Mice		168	7523		7691
Rats			24		24

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIGNATURE OF HEADQUARTERS RESEARCH FACILITY OFFICIAL

DATE SIGNED

11/26/03

DEC 01 2003

See attached form for additional information.

Interagency Report Control No. *92*

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0116  
CUSTOMER NUMBER: 695

FORM APPROVED  
OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY**  
( TYPE OR PRINT )

Xenobiotic Laboratories, Inc.  
107 Morgan Lane  
Plainsboro, NJ 08536

Telephone: (609) -799-2295

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	0	16	0	1	17
5. Cats	0	0	0	0	0
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

**ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIGNATURE

( or Print )

DATE SIGNED

11-25-03

APHIS FC  
( AU )

*QAN*

### Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 22-R-0116

2. Number 1 (not on study) of animals used in this study.

3. Species (common name) Beagle Dog of animals used in the study.

4. Explain the procedure producing pain and/or distress.

Dog accidentally got neck/head stuck in chain provided to aid in cleaning process. Dog struggled causing strangulation + death. Dog was not on study

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

None. not on study. Accidental death.  
All chains immediately removed + USDA + vet notified.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency \_\_\_\_\_ CFR \_\_\_\_\_

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0117

CUSTOMER NUMBER: 701

FORM APPROVED  
OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY**  
( TYPE OR PRINT )

Barton'S West End Farms, Inc.  
161 Janes Chapel Road  
Oxford, NJ 07863

Telephone: (908) -637-4427

NOV 25 2003

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F. TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	0	219	26	0	245
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	12	0	0	12
9. Non-human Primates	7	0	0	0	0
10. Sheep	0	0	1	0	1
11. Pigs	2	0	47	0	47
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

**ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

DATE SIGNED

24 NOV 03

Customer ID and Site Address:

ID: 701

Po Box 290

Lakewood, NJ 18430 0290

County: Ocean

Telephone



UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0118  
CUSTOMER NUMBER: 1672

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

Pediatric Cardiology  
137 Pavalon Avenue  
Long Branch, NJ 07740

Telephone: (908) -870-1611

OCT 07 2003

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

None used.  
will start soon.

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIGNATURE OF C

DATE SIGNED

9/30/03

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0123  
CUSTOMER NUMBER: 1824

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

County College Of Morris  
Veterinary Tech. Program  
214 Center Grove Road  
Randolph, NJ 07869

Telephone: (973) -328-5340

OCT 02 2003

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	4	0	0	4
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )

DATE SIGNED

9/25/03

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0125  
CUSTOMER NUMBER: 11697

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

Hackensack University Medical Center  
Institute For Biomedical Research  
David Joseph Jurist Research Bldg  
30 Prospect Ave  
Hackensack, NJ 07601

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs			9		
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits			5		
9. Non-human Primates					
10. Sheep					
11. Pigs	1		45		
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

DATE SIGNED

10-09-03

**Customer ID and Site Address:**

**ID: 11697**

**Institute For  
Biomedical Research  
Hackensack, NJ 07601  
County: Bergen**

**Telephone  
(201)996-2879**

DEC 02 2003

See attached form for additional information.

Interagency Report Control No.:

PSM

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0130  
CUSTOMER NUMBER: 1701

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

Qualtech Laboratories, Inc.  
104 Green Grove Road  
Ocean, NJ 07712

Telephone: (908) -918-0207

732

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F. TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	0	0	0	0	0
5. Cats	0	0	3	0	3
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

S

DATE SIGNED

11-28-03

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UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0131  
CUSTOMER NUMBER: 16333

FORM APPROVED  
OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY**  
( TYPE OR PRINT )

Kraft Foods North America, Inc  
Sherburne Pet Food Testing Center  
200 De Forest Avenue  
East Hanover, NJ 07936

Telephone: (607) -674-9414

**NOV 21 2003**

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Alached Listing

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F. TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	118	118	0	0	118
5. Cats	0	51	0	0	51
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

**ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual res teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
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**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIGNATURE OF C.E.O.

DATE SIGNED

10/30/03

SEP 23 2003

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 211.

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0132  
CUSTOMER NUMBER: 188

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

Gibraltar Laboratories, Inc.  
122 Fairfield Road  
Fairfield, NJ 07004

Telephone: (973) -227-6882

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F. TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals ( mice )	100	100	0	0	100

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
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- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIG:

( Type or Print )

DATE SIGNED

9/19/03

OCT 29 2003

See attached form for additional information.

Interagency Report Control No. *ofan*

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

1. CERTIFICATE NUMBER: 22-R-0133  
CUSTOMER NUMBER: 406

FORM APPROVED  
OMB NO. 0579-0036

Public Health Research Institute  
225 Warren Street  
Newark, NJ 07103

Telephone: (973)-972-9150 (no longer in use)  
New Telephone No. 973-854-3100

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	1	44	0	45
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inx brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIGNATURE OF C.I

or Print )

DATE SIGNED

10/28/03



**3. REPORTING FACILITY** ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

## ASSURANCE STATEMENTS

- DATE SIGNED \_\_\_\_\_

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0135  
CUSTOMER NUMBER: 22320

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

Transave Inc  
11 Deer Park Drive Suite 117  
Monmouth Junction, NJ 08852  
Telephone: (732) -438-9434  
OCT 24 2003

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHS Form 7023A )

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F. TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0			
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

rint )

DATE SIGNED

10/24/03

Customer ID and Site Address:

ID: 22320

11 Deer Park Drive

Suite 117

Monmouth Junction, NJ 08852 1923

County: Middlesex

Telephone *732-438-9434 Ext 25*

Registration Number: 22-R-0036

November 22, 2003

Elizabeth Goldentyer, DVM  
**UNITED STATES DEPARTMENT OF AGRICULTURE**  
Animal and Plant Health Inspection Service  
Regulatory Enforcement and Animal Care  
Eastern Region Office  
920 Main Campus Drive  
Suite 200  
Raleigh, NC 27605

Dear Dr. Goldentyer:

Listed below are comments to accompany the annual report of research facilities for site number 1.

The environmental enrichment program has exceptions for social housing for nonhuman primates. Twenty-three rhesus monkeys are housed separately due to special study requirements for controlling and monitoring food consumption as part of the research projects. Twenty cynomolgus monkeys were housed separately for brief periods (1-2 days) while participating in telemetric monitoring studies. All the animals are included in all the other aspects of the environmental enrichment program. The protocols with the exemption are approved by the IACUC and reviewed during the semi-annual program review.

One exception to the canine exercise program is to be reported and involved eight animals. It involved the use of special canine metabolism cages for drug metabolism studies or urine collection studies. The canine metabolism cages provide greater than 100%, but less than 200% of required space for exercise. The period of time in the cages vary with the test compound and study. Most of the studies lasted for 24 hours and the longest lasted for 42 days. Positive human interaction is greatly increased during this period. The protocols with the exemption are approved by the IACUC and reviewed during the semi-annual program review.

Listed below are comments to accompany the annual report of research facilities for site Number 2.

A. Summary of exceptions to the regulations and standards:

There were some exemptions to the pair-housing requirement of our IACUC approved program for the psychological well-being of non-human primates. Most exemptions were for approximately two weeks in duration. A total of five hundred and forty-four non-human primates were exempted from social housing for reasons which include: acclimation and health assessment during the beginning of the quarantine period, establishing suitable cage mates and preparing social caging.